Decision Memo for Acupuncture for Osteoarthritis (CAG-00175N)

Decision Summary

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Decision Memo

This decision memorandum does not constitute a national coverage determination (NCD). It states CMS's intent to issue an NCD. Prior to any new or modified policy taking effect, CMS must first issue a manual instruction giving specific directions to our claims-processing contractors. That manual issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual. Policy changes become effective as of the date listed in the transmittal that announces the Coverage Issues Manual revision.

To: Administrative File CAG: #00175N
Acupuncture for the Treatment of Osteoarthritis

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Subject: Coverage Decision Memorandum for Acupuncture for Osteoarthritis

Date: October 10, 2003

I. Decision

CMS has determined that the evidence is not adequate to conclude that the use of acupuncture is reasonable and necessary for the treatment of osteoarthritis and, therefore, CMS will continue its noncoverage policy for acupuncture.

II. Background

On December 2, 2002, CMS began a national coverage determination process for acupuncture for osteoarthritis.

Osteoarthritis is the most common form of arthritis in the United States and occurs in most adults over 60 years of age. Osteoarthritis is often referred to as "degenerative joint disease" and is common in the knees and hips, followed by the cervical and lumbar spine, as well as the fingers and big toe. It is characterized by the breakdown of a joint's cartilage. Cartilage is the part of a joint that cushions the ends of bones. Cartilage breakdown thus causes bones to rub against each other, causing pain and loss of movement. This painful osteoarthritis typically exhibits morning stiffness, worsens with weight bearing and activity, and improves with rest. Unlike rheumatoid arthritis and other inflammatory arthritides, inflammation (if present) in osteoarthritis is usually mild and localized to the affected joint. Although the causes of OA are not completely understood, important contributory factors include biomechanical stresses, biochemical changes and genetic factors affecting the cartilage and bone.

There is no known cure or uniformly effective treatment for osteoarthritis. Treatment designed for the individual patient, however, can help to alleviate pain, maintain and/or improve joint mobility, and limit functional impairment. In September 2000, the American College of Rheumatology (ACR) published updated recommendations for the pharmacologic and non-pharmacologic management of osteoarthritis of the hip and knee. While a wide range of drugs are available for patients with osteoarthritis, drug therapy for pain management is most effective when combined with nonpharmacologic strategies, such as patient education, physical and occupational therapy. The ACR also noted that patients with severe symptomatic osteoarthritis, who have pain that has failed to respond to medical therapy and who have progressive limitation in their activities of daily living, should be referred for evaluation by an orthopedic surgeon. Surgical outcomes for osteoarthritis depend upon the timing of surgery, the experience of both the surgeon and hospital where the procedure is performed, as well as each patient's preoperative medical status, postoperative management and rehabilitation. For agents under investigation, the ACR noted that therapeutic approaches such as acupuncture are difficult both to evaluate and to recommend because of large placebo effects and the lack of adequate sham-controlled studies.[1]

While there is a diversity of theoretical models and techniques that are all described as acupuncture, all models and forms seek to treat and prevent symptoms and conditions through either: 1) the insertion of needles or “needling” at specifically chosen points on the body, or 2) other “non-needling” techniques focused on these points. Traditional Chinese medicine (TCM) theorizes that there are more than 2000 acupuncture points connecting 12 main and 8 secondary pathways called meridians. TCM practitioners theorize that these points connect with energy (*qi*) conducting meridians that affect the spiritual, emotional, mental and physical balance of the opposing forces of yin and yang. TCM practices are intended to improve the flow of *qi* and treatment approaches may include herbal preparations and lifestyle or dietary advice in addition to traditional Chinese acupuncture individualized to each patient’s signs and symptoms.

Modern acupuncturists or medical acupuncturists (terminology sometimes used interchangeably) do not necessarily adhere to TCM theories to support their practices. Some acupuncturists and scientists have recognized that it is difficult to identify an empirical basis for TCM's theories concerning energy conducting meridians and have instead theorized that needling may enhance or inhibit nerve conduction. The diversity of terminology and complexity of explanatory models has thus resulted in considerable variation in acupuncture techniques.

Variations to traditional Chinese acupuncture include shallow needling, intradermal needling or intramuscular needling with or without *de qi*.[2] Acupuncturists may additionally seek a sensation of tenseness or dragging to the needles obtained by twirling, plucking or thrusting of acupuncture needles. There are also numerous variations of manually or electrically stimulated "needling" techniques, as well as multiple "non-needling" acupuncture techniques.[3]

Summarizing the current status and central issues in credentialing acupuncturists and other complementary and alternative medicine (CAM) providers, Eisenberg, *et al.* (2002) noted that: "Acupuncture, first licensed by Nevada, Oregon, and Maryland in 1973, currently is licensed in 42 states and the District of Columbia. More than 14,000 practitioners are licensed in the United States, and an additional estimated 3000 medical doctors have studied formally and incorporate acupuncture into their practices. Of the more than 70 schools of acupuncture in the United States, 37 are accredited by and 9 are in candidacy status with the U.S. Department of Education recognized Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM). About one third of the states that license non-physician acupuncturists require graduation from an ACAOM school or one with an equivalent curriculum. In addition, approximately one third of licensing states require the study of biomedical sciences, including anatomy, physiology, and pathology. The National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) offers separate certification programs in Acupuncture, Chinese Herbology, and Oriental Bodywork Therapy. As with chiropractic, almost all states licensing acupuncturists require passage of a national written examination offered by NCCAOM. Twelve states also require passage of the NCCAOM practical examination."[4]

"Credentialing problems persist. First, state requirements to practice acupuncture vary. In many states, acupuncture training requirements for medical doctors, dentists, and other allopathic providers are minimal or nonexistent. Some states permit licensed CAM providers, such as chiropractors, to practice acupuncture (with varying levels of training) whereas other states prohibit it. Second, states vary in their defined scope of practice for acupuncture and Oriental medicine…. Third, only 14 states have an independent board of acupuncture or Oriental medicine; in other states, acupuncturists are under the board of medical examiners or regulated by the departments of commerce or health…. [Fourth], approximately one quarter of the states licensing acupuncturists require prior referral from, diagnosis by, or collaboration with a licensed medical doctor."[5]

The American Board of Medical Specialties (ABMS) is the most widely recognized U.S. organization of 24 approved medical specialty boards. ABMS certification of physicians is intended to provide assurance to the public that those certified by member boards have successfully completed an approved training program and an evaluation process assessing their ability to provide quality patient care in their specialty. No medical specialty board for acupuncture or medical subspecialties with approved certificates for acupuncture are recognized or approved by the ABMS, and no physicians have been certified by the ABMS to perform acupuncture.[6] The American Board of Medical Acupuncture, which was independently established by the American Academy of Medical Acupuncture on April 26, 2000, is not a member specialty, medical subspecialty, approved member board or associate member of the ABMS. This lack of uniformity in credentialing creates additional issues with respect to what constitutes an acupuncturist and therefore what constitutes an acupuncture procedure.

III. History of Medicare Noncoverage for Acupuncture

CMS issued a national noncoverage determination for acupuncture in the Medicare Coverage Issues Manual (CIM) May 1980, Section 35-8 (Acupuncture – Not Covered).

CMS's Center for Medicare Management (CMM) has determined that acupuncture could potentially fall within the benefit category set forth in section 1861(b)(3) (inpatient hospital services), 1861(s)(1) (physician services), 1861(s)(2)(A) (services "incident to" a physician's professional service of the kind that are commonly furnished in a physician's office) or 1861(s)(2)(B) (hospital services "incident to" physicians' services rendered to outpatients) of the statute.

IV. Timeline of Recent Activities

September 30, 2002	Mr. Jay Silverman, a beneficiary from Leesburg, Florida, submitted a letter requesting that CMS reconsider its noncoverage of acupuncture.
December 2, 2002	CMS staff worked with requestor to complete formal request, including gathering appropriate evidence, and formally accepted request for review of acupuncture for osteoarthritis.
September 4, 2002	Referred to the Agency for Healthcare Research and Quality (AHRQ) for a technology assessment on the broad topic of acupuncture. This request was refined when the formal request for specific indications was received.

June 27, 2003	Acupuncture for Osteoarthritis Technology Assessment received from AHRQ.

V. Food and Drug Administration (FDA) Status

Since 1973, the FDA has considered acupuncture devices, including needles, as investigational medical devices. In March 1996, the FDA announced that acupuncture needles had been reclassified from Class III (experimental) medical devices to Class II (non-experimental but regulated) medical devices for general acupuncture use by licensed registered or certified practitioners. Class II devices involve less stringent controls such as good manufacturing procedures and proper labeling, but data demonstrating clinical effectiveness is not required for these devices. At the time of the 1996 reclassification, no scientifically convincing data had been presented to FDA demonstrating efficacy for any acupuncture device for any medical indication.

The FDA defined an acupuncture needle as a device intended to pierce the skin in the practice of acupuncture, and that the device consists of a solid, stainless steel needle which may have a handle attached to facilitate the delivery of acupuncture treatment. The FDA requires manufacturers of acupuncture needles to label them for single use only. Acupuncture needles must also bear a prescription labeling statement which restricts their use to qualified practitioners as determined by the states, and manufacturers must provide information about device material biocompatibility and sterility.[7,8] Any other use would be an off-label use.

CMS assesses relevant health outcomes, above and beyond the safety and effectiveness regulatory mandate of the FDA. Although a device must receive FDA approval or clearance for at least one indication to be eligible for Medicare coverage, except for a category B device under an investigational device exemption (IDE) clinical trial (60 FR 48417, September 19, 1995), FDA approval/clearance alone does not entitle that device to coverage. The device must fall under a Medicare benefit category and be determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member to be covered by CMS. CMS has the authority to conduct a separate assessment of a device's appropriateness for Medicare coverage, including whether it is reasonable and necessary specifically for its intended use for Medicare beneficiaries (*see e.g.*, 60 FR 48417, 48420 (September 19, 1995). Under a premarket approval application (PMA) review, the FDA determines whether or not there is reasonable assurance of safety and effectiveness for the device's intended use that is stated in its proposed labeling. Medicare NCDs consider the medical benefit and clinical utility of an item or service in determining whether the item or service is considered reasonable and necessary under the Medicare program. CMS determines whether or not the intervention improves net health outcomes in the Medicare population at least as well as established treatments. Thus, FDA PMA approval by itself is not sufficient for making a determination concerning Medicare coverage.

As we similarly stated in 66 FR 58788, 58797 (November 23, 2001) with regard to FDA 510(k) clearance, "[t]he criteria the FDA uses in making determinations related to substantial equivalency under section 510(k) of the Food, Drug, and Cosmetic Act is significantly different from the scientific evidence we consider in making "reasonable and necessary" determinations under Medicare. FDA does not necessarily require clinical data or outcomes studies in making a determination of substantial equivalency for the purpose of device approval under section 510(k) of the Food, Drug, and Cosmetic Act. Medicare NCDs consider medical benefit and clinical utility of an item or service in determining whether the item or service is considered reasonable and necessary under the Medicare program. Thus, a substantial equivalency approval under section 510(k) of FDA is not sufficient for making determination concerning Medicare coverage."

VI. General Methodological Principles

When making national coverage decisions, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding of reasonable and necessary. The evidence may consist of external technology assessments, internal review of published and un-published studies, recommendations from the Medicare Coverage Advisory Committee, evidence-based guidelines, professional society position statements, expert opinion, and public comments. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) specific clinical questions relevant to the coverage request can be answered conclusively; and 2) the extent to which we are confident that the intervention will improve net health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the relevance of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention’s risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has unique methodological aspects.

1. Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.

- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to help ensure adequate numbers of patients are enrolled to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias)
- Co-interventions or provision of care apart from the intervention under evaluation (confounding)
- Differential assessment of outcome (detection bias)
- Occurrence and reporting of patients who do not complete the study (attrition bias)

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study's selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess the evidence.

2. Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage decisions for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. The goal of our determination process is to assess net health outcomes, and we are interested in the results of changed patient management not just altered management. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

3. Assessing the Relative Magnitude of Risks and Benefits

CMS determines whether an intervention is reasonable and necessary by evaluating its risks and benefits. For all determinations, CMS evaluates whether reported benefits translate into improved net health outcomes. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

4. Specific Methodological Issues in Acupuncture Research

Under "Issues in Acupuncture Treatment and Research," the 2002 Alberta Heritage Foundation for Medical Research (AHFMR) Health Technology Assessment of Acupuncture: Evidence from Systematic Reviews and Meta-analyses (2002)[9] **discussed three critical study design issues that aided in framing CMS's subsequent evidence analysis:**

- Selection of credible control groups
- Complexities and variability of acupuncture treatments
- Overall study design and assessment of methodological quality.

Selection of Credible Control Groups

The selection of appropriate control groups poses a challenge for all acupuncture research and is relevant to evaluate any relief of pain that may be associated with acupuncture for osteoarthritis. Controls can range from placebo or sham procedure controls, to standard care or no treatment at all. The use of placebo or sham versus standard care or no treatment, as well as the effects of sham procedures on outcomes, are issues of debate in the acupuncture literature. Compared to non-placebo controls who know they are not receiving treatment, placebo controls enable blinding and can potentially decrease a study's dropout rate. A placebo needle has been developed, which mimics visual and tactile sensations of acupuncture, but which disappears into the handle and does not break the skin. Sham laser acupuncture has also been utilized, which uses visual and acoustic signals similar to those found during active laser acupuncture. Additional placebo or sham procedures include use of non-traditional acupuncture points, superficial puncturing of the skin without stimulation, introduction of a sensation without puncturing in acupressure, and stimulators without connector cables in electroacupuncture.

Overall, these placebo or sham procedure controls have the potential to increase patient's perception of receiving real acupuncture and also enable double blinding. However, the most commonly used sham procedure control is needling done at theoretically irrelevant sites. While initially thought that acupuncture at these sites would have no effect, some believe that inserting a needle anywhere in the body or applying pressure to any site evokes a response. Evocation of this response can also be found with the other above-mentioned placebo controls.

Complexities and Variability of Acupuncture Treatments

Since acupuncture includes a diverse range of philosophies and treatment styles, the most accurate determination of acupuncture's effectiveness should include the evaluation of each well-defined approach, rather than evaluating an entire family of treatments as a single approach. However, many types and variations of traditional Chinese medicine (TCM) acupuncture are often combined and compared in systematic reviews. For example, while manual and electrical stimulation are seldom compared, acupressure and electroacupuncture have nonetheless been considered the same in many systematic reviews. Multiple acupuncture styles are also utilized. Ear acupuncture is perhaps the most widely used, although other systems such as scalp, hand, foot, nose and abdominal acupuncture are also considered specialties. TCM and formula acupuncture represent two different styles, but these are also often grouped together in reviews. TCM focuses on a balanced system and uses point selection based on symptoms, pulse and tongue diagnoses. The choice of points used in TCM may vary from day to day as the balance of energy (*qi*) shifts. The formula or standardized approach uses the same prescription of points for each patient. While better suited for research, this approach may not reflect actual community practice. In many ways, individualized acupuncture diagnosis and treatment is similar to psychotherapy or physiotherapy, where the therapist's skill, contact and bond with the patient may be as important in producing an effect as the treatment strategies themselves. In such settings, acupuncture therapy is adjusted according to subtle shifts, as they occur, rather than continuing with a standard acupuncture approach.

There is also variability in the technique of needle insertion and manipulation, which may influence effectiveness but is often not recorded. Diameter, length, depth of insertion, duration of retention, number of needles per treatment, temperature of needles, number of treatments and needle composition may likewise influence the outcome. Low levels of agreement have also been reported for expert acupuncturists independently evaluating the adequacy, choice and relevance of acupuncture points utilized in clinical studies.

Overall Study Design and Assessment of Methodological Quality

Many primary studies and some systematic reviews lack either a strong research design and/or an adequate description of study design on which results can be evaluated and compared. Small sample size (whether relative to the anticipated magnitude of effect and allowable standard error or absolute, such as less than 10 patients in each treatment arm) has led to under-powering of results. Some reviews report positive correlations between low methodological study quality and positive outcomes.

VII. Evidence

A. Introduction

The following summary represents the body of evidence for this decision memorandum. The evidence reviewed about the use of acupuncture for the treatment of patients with osteoarthritis includes the peer-reviewed literature evaluated by both external and internal technology assessments and expert opinion.

The sole health outcome of interest to CMS in this decision memorandum is the impact of acupuncture on pain reduction in patients with osteoarthritis.

Pain relief can be measured on a visual analog scale (VAS). A VAS asks the patient to rate his or her experience of pain severity on a 1 to 100 mm scale. This scale is not specific to acupuncture treatments but has proven validity and reliability.[10] Pain relief can also be measured using the Western Ontario and McMaster Universities (WOMAC) osteoarthritis scale. This disease-specific, self-administered, health status questionnaire defines symptoms of pain, stiffness and physical function for patients with osteoarthritis of the hip or knee and has proven validity and reliability. The greater the WOMAC score, the more pain and dysfunction the patient reports.[11] The Lequesne scale (also known as the Lequesne Algofunctional Index) is designed to measure patient status at different stages of osteoarthritis and is said to be of particular value in assessing osteoarthritis in weight-bearing joints.[12]

To assess a study's methodological quality, four of five criteria in the Jadad scale deal with randomization and blinding. The Jadad method (maximum score = 5) awards one point for a study's description of its randomization, double blinding and withdrawals and/or dropouts, and awards or deducts one point dependent upon a study's appropriate or inappropriate description of its randomization and double blinding methods.[13]

B. Discussion of evidence reviewed

1. Specific Decision Memorandum Question

CMS's evidence summary and analysis focuses on the following question: "Is there evidence of adequate methodological quality to conclude that the use of acupuncture significantly and reliably reduces pain in Medicare patients with osteoarthritis?"

2. External Technology Assessment

Assisting CMS in the initial search of the literature, AHRQ identified the following two methodologically sound technology assessments:

- United Kingdom National Health Service (NHS) Center for Reviews and Dissemination: Effective Health Care on Acupuncture (2001)[14]
- Alberta Heritage Foundation for Medical Research (AHFMR) Health Technology Assessment of Acupuncture: Evidence from Systematic Reviews and Meta-analyses (2002)[15]

AHRQ then performed a technology assessment (TA) to search for additional randomized controlled trials (RCTs) and reviews of acupuncture for osteoarthritis performed since the 2001 NHS and 2002 AHFMR publications. AHRQ reviewed the abstracts of all RCTs identified and searched for ongoing clinical trials of acupuncture for osteoarthritis.

The 2001 NHS report evaluated acupuncture for chronic pain, including osteoarthritis, and was based predominantly on a review of systematic reviews conducted by the Complementary Medicine Field of the Cochrane Collaboration. Included were clinical trials of acupuncture. The NHS reviewed all systematic reviews on acupuncture from 1989 to July 2000. There were no language restrictions. In 2001 a second search was conducted to find any new reviews and RCTs. Where no systematic review was available, all RCTs on that topic were included.

The 2002 AHFMR assessment evaluated acupuncture for the treatment of chronic pain, but the one systematic review of acupuncture identified by AHFMR for the symptomatic treatment of osteoarthritis by Ernst[16] was excluded because it did not use a tool to evaluate methodological quality. Therefore, no systematic reviews for acupuncture specifically for osteoarthritis were included. The AHFMR report, however, provided discussion of specific methodological issues in acupuncture research that formed the basis for the earlier fourth section in this CMS decision memorandum on general methodological principles. Detailed descriptions of the NHS review's methodology, the AHFMR assessment's methodology and AHRQ's complete search strategy used to identify all studies listed are provided in Appendices B, C and D of AHRQ's TA.

The 2001 NHS report evaluated two systematic reviews, including one by Ezzo and colleagues[17] on acupuncture for knee osteoarthritis, as well the systematic review by Ernst[18] that was excluded by the 2002 AHFMR assessment.

Ezzo, *et al.* (2001) reviewed 7 studies of osteoarthritis of the knee that were identified as RCTs. These studies suggested that acupuncture is more effective than being on a waiting list for treatment or treatment as usual. The studies did not find a benefit for acupuncture compared to physical therapy. The studies also did not find a benefit for acupuncture compared to sham acupuncture for improving function. Ezzo, *et al.* reviewed three studies with sham acupuncture as a control. Two studies[19,20] found larger improvements in pain with acupuncture compared to sham, while the third by Berman and colleagues (1999) did not.[21] Ezzo's review noted that in the two studies that showed a benefit the sham acupuncture consisted of needles placed at distal non-acupuncture points, which were referred to as "minimal sham". In the 1999 Berman study, which did not show a benefit for sham acupuncture, the sham acupuncture was at sites one inch adjacent to the real points and may have inadvertently elicited an analgesic response. Ezzo's review also noted that some studies were small and may be underpowered to find a positive effect. Other methodological problems in some of the studies included lack of blinding of patients and outcomes assessors, as well as lack of description of dropouts and withdrawals.

Ernst (1997) reviewed 13 studies, of which 12 were identified as being controlled clinical trials or RCTs. Ernst concluded that most trials suffered from methodological flaws, but that the most rigorous studies suggested that acupuncture is not superior to sham needling in reducing the pain of osteoarthritis, i.e., both real and sham needling are equally effective. This would suggest that either sham needling has similar specific effects as real acupuncture or that both methods are associated with considerable non-specific effects. Other methodological problems in some of the studies included heterogeneous samples, infrequent therapy sessions, no formal test statistics, groups not equal at entry, and essential details missing.

AHRQ identified one additional follow-up study by Berman and colleagues[22] not included in the NHS report. Berman, *et al.* (2000) reviewed 8 studies of the use of acupuncture in treating osteoarthritis as part of their larger review of the use of acupuncture for rheumatological conditions. Three studies were identified as being RCTs. However, Berman, *et al.'s* (2000) review classified Christensen, *et al.'s* 1992 study and Berman, *et al.'s* own 1999 study as time series, although the abstracts of these studies indicate that they were randomized.[23,24] A 1982 study by Junnila[25] was cited by both Ernst's 1997 and Berman, *et al.'s* (2000) review, both of which refer to Junnila's study in their summary tables as non-randomized. However, the text of the Berman, *et al.* (2000) systematic review describes the Junnila study as randomly assigning patients. In fact, Junnila described a sequential study in which successive patients treated either with medication or acupuncture were done years apart and were clearly not randomized. Berman, *et al.* (2000) found that, for the studies they classified as RCTs, there were no significant benefits for acupuncture compared to sham acupuncture. Furthermore, none of the studies had sufficient power to detect a difference between acupuncture and sham acupuncture, and there were significant improvements compared to baseline for both acupuncture and sham acupuncture groups. Berman, *et al.* (2000) suggested that this may be because puncturing the skin at any position elicited an analgesic response or that the sham sites chosen were actually active acupuncture sites.

AHRQ likewise identified four RCTs published since the last systematic review of acupuncture for osteoarthritis.[26,27,28,29] The results of these trials were consistent with the results of previously reviewed studies and are subsequently described in the synthesis of evidence section of CMS's internal technology assessment.

In summarizing, AHRQ noted that a key issue in studies of acupuncture is the effect of sham acupuncture. Most studies on acupuncture for osteoarthritis found a benefit for both acupuncture and sham acupuncture compared to baseline but did not find a benefit for acupuncture compared to sham acupuncture. The systematic reviews had somewhat different conclusions based on their interpretation of the evidence, but all reviewers agreed that more research is necessary to understand the effects of sham acupuncture. AHRQ additionally noted that it has been difficult to determine whether the effect observed is a non-specific placebo effect because of the issues around the design of sham acupuncture procedures in RCTs. Those problems arise from the lack of clear definition of what constitutes “acupuncture” and through what mechanisms acupuncture is purported to work. AHRQ thus concluded that the currently available evidence is insufficient to determine whether acupuncture has a specific beneficial effect for osteoarthritis, and that new ongoing studies should help to clarify the potential specific effect, if any, of acupuncture for osteoarthritis. The complete AHRQ TA can be accessed via its hyperlink on CMS’s tracking sheet for this issue at http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=84

3. Internal Technology Assessment

Literature Search

Supplementing the information received from the requestor and AHRQ’s initial literature search, CMS itself extensively searched PubMed (1990 to present) for RCTs and systematic reviews evaluating the use of acupuncture for osteoarthritis. CMS likewise searched the Cochrane Collaboration, the NHS Centre for Reviews and Dissemination, and the INAHTA databases for all systematic reviews and technology assessments. Keywords used in CMS’s search were “acupuncture” and “osteoarthritis.” RCTs must have presented original data, included greater than or equal to 10 patients, examined health outcomes, and been published as full-length articles in peer-reviewed, English language journals. Uncontrolled studies and abstracts were excluded.

Summary of Evidence

Searching all databases using the aforementioned search strategy, CMS identified no new RCT of acupuncture for osteoarthritis. Methods and results from the four most recent 2001 RCTs, found but not fully discussed by AHRQ, are detailed in our “Synthesis of Evidence” section.

CMS did, however, identify one review of acupuncture for osteoarthritis by Bandolier (2000) which was not commented upon in AHRQ’s TA. The strengths and weaknesses of the published literature, as evaluated by CMS staff and all reviewers (including Bandolier), are summarized in our “CMS Analysis” section.

The sole health outcome of interest to CMS in this decision memorandum is the impact of acupuncture on pain reduction. As AHRQ noted, most studies on acupuncture for osteoarthritis found that both acupuncture and sham acupuncture provided benefit, i.e., relief of pain compared to baseline, but did not find a benefit for acupuncture compared to sham acupuncture. AHRQ also briefly commented upon the evidence provided by four recent RCTs of acupuncture for osteoarthritis published since the 2001 NHS systematic review. These RCTs, including one re-analysis of data from previously studied patients, are described below in greater detail.

Haslam (2001) evaluated patients awaiting total hip arthroplasty to compare the effectiveness of acupuncture versus advice and exercises on patients' perceived pain and disability. At the start of the study, 16 patients were randomly allocated to acupuncture (group A) and 16 patients to advice and hip exercises (group B). Group A received one session of acupuncture per week over a 6-week period. Group B received an advice sheet with recommended self-help and exercises for osteoarthritis that were demonstrated and practiced at session one and then reviewed at 3 and 6 weeks. Haslam's study thus included a total of either 6 acupuncture sessions or 3 advice and exercise sessions. The study did not include either a sham acupuncture or a no treatment control group. Mean age was 66 years in group A (13 women and 3 men), and mean age was 68 years in group B (8 women, 4 men and 4 withdrawals). Patients were assessed for pain and functional ability pre-treatment, immediately post-treatment and at 8 week follow-up using a modified WOMAC questionnaire. This shortened WOMAC may have reduced the validity and reliability of the outcome measure. There was significant improvement in group A (decrease in WOMAC score) immediately post-treatment at the end of the 6 week course of acupuncture ($p = .002$), and this was maintained at 8 weeks follow-up ($p = .03$). There were no significant changes in group B. Group A remained intact during the 6-week treatment period, whereas 4 patients withdrew from group B. Between the post-treatment assessment and the 8-week follow-up, 1 patient withdrew from group A, and 3 further patients withdrew from group B. Dropouts thus totaled 7 of 16 original patients in group B, compared with loss of only 1 patient in group A.[30]

Singh, *et al*. (2001) re-analyzed data from Berman, *et al.'s* (1999) RCT to determine whether demographic, medical history or arthritis assessment data influenced the outcome and rate of decay of osteoarthritis patients treated with acupuncture. In 1999, Berman's group randomized 73 patients diagnosed with symptomatic osteoarthritis of the knee to acupuncture (36 patients) or standard care with oral medications (37 patients). 15 patients did not complete or dropped out of the study. Patients were treated for 8 weeks and followed up at 12 weeks (4 weeks after the cessation of treatment). Patients in the standard care control group were offered acupuncture after 12 weeks, and data from those accepting was pooled with the original acupuncture group for within-group analysis. Berman's primary outcome measures included the self-scored WOMAC and Lequesne scales at baseline, 4, 8 and 12 weeks. Results showed that patients randomized to acupuncture improved at 4 and 8 weeks ($p < .001$) on both the WOMAC and Lequesne indices compared to those who received standard care alone. There was a slight decline at 12 weeks, i.e., 4 weeks after the cessation of acupuncture treatments.[31]

The 15 patients who dropped out of Berman, *et al.'s* (1999) study were significantly different from the 58 patients who completed the study in age ($p = .05$), disease duration ($p = .04$) and score on the WOMAC pain subscale ($p = .05$). Patients who dropped out were younger, had experienced longer disease duration and had higher pain scores at baseline. The sample analyzed by Singh, *et al.* (2001) included patients who received acupuncture for osteoarthritis as part of the treatment group during the RCT or those in the standard care group who were offered acupuncture (i.e., crossovers) once the control period was over. Sample size for Singh's outcomes analysis of this same data set was 60 patients at 4 weeks, 58 patients at 8 weeks, and 52 patients at 12 weeks. With WOMAC scores partitioned into equal quartiles, the group with the least disability and pain rebounded to original levels to a greater degree than did those initially more disabled. Demographic and medical history data did not appear to mediate patients' improvement.[32]

Tillu, *et al*. (2001) studied 44 patients with advanced knee osteoarthritis awaiting total knee joint replacement surgery. Patients were randomly allocated into two groups, group A (18 women and 4 men) receiving unilateral acupuncture to the most affected knee only and group B (17 women and 5 men) receiving bilateral acupuncture to both knees. Mean age was 72 years (ranging from 53 – 90 years) in group A and 73 years (ranging from 64 –92 years) in group B. All patients received six acupuncture treatments at weekly intervals, and a blinded observer assessed knee function pre-treatment and at two and six months from the commencement of treatment. There was a statistically significant improvement in both subjective and objective parameters (VAS scores with $p < .01$) in both the unilateral and bilateral acupuncture groups at the end of two months, and this improvement was sustained for six months. There was no statistically significant difference between the groups. Tillu and colleagues concluded that unilateral acupuncture is as effective as bilateral acupuncture in increasing function and reducing the pain associated with knee osteoarthritis.[33]

Fink, *et al*. (2001) evaluated 67 patients with hip osteoarthritis who had not started any physical therapy or medical treatment and who had not planned a total hip replacement. Patients were randomly assigned to either group 1 (19 women and 14 men) for acupuncture treatment with traditional needle placement and manipulation, or to group 2 (24 women and 8 men) where needles were placed at least 5 cm away from classic acupuncture points or trigger points and not manipulated. Mean age was 61.4 ± 8.6 years in group 1, and mean age was 63.8 ± 9.5 years in group 2. Outcome parameters included pain as measured by the VAS, as well as functional impairment, activities of daily living and overall satisfaction at baseline pre-treatment and at 2 weeks and 2 months post-treatment. For all parameters, there was significant improvement versus baseline ($p < .005$ for pain intensity on the VAS) in both groups at both 2 weeks and 2 months, but there was no significant difference between the two treatment groups. Fink's group did not have an explanation for the positive effect of both treatments in their study population. The authors concluded that needle placement in the area of the affected hip joint had a "positive effect on the symptoms of hip osteoarthritis, although no special knowledge of acupuncture is needed."[34]

4. Medicare Coverage Advisory Committee (MCAC)

This issue was not referred to the MCAC.

5. Evidence-Based Guidelines

CMS identified no evidence-based guidelines for the use of acupuncture for the treatment of osteoarthritis.

6. Professional Society Position Statements

CMS received no formal position statements or professional society guidelines regarding the use of acupuncture for the treatment of osteoarthritis.

7. Expert Opinion

CMS received two letters from individual physicians with an interest in the coverage decision(s) for acupuncture:

- A letter from a diplomat of the American Board of Medical Acupuncture stating: "…My experience with both of these conditions [fibromyalgia and osteoarthritis] is that, while acupuncture cannot cure either condition, it may cause significant improvement in the symptoms if used on a regular basis."

- In another letter from the Vice President of Clinical Operations and MD at a community medical center: "… I practice acupuncture and find it very beneficial for osteoarthritis of the back, knee and shoulder in particular. Patients who undergo treatment utilize less medications, which put their GI tract and kidney function at risk. I believe that acupuncture should be a covered benefit for Medicare participants who suffer from osteoarthritis…."

8. Public Comments

CMS received two public comments regarding the use of acupuncture for the treatment of osteoarthritis. Both comments were in favor of a national Medicare coverage policy.

9. Future Research

The state of acupuncture research remains investigational. Adequate study designs, such as large multicenter RCTs with three arms including real acupuncture, sham acupuncture and placebo, are still being developed and tested. Evidence to determine potential utility of acupuncture for osteoarthritis may be obtained from RCTs including measurements of pain and quality of life using validated instruments, larger sample sizes and long-term follow-up.

Ongoing Clinical Trials

Issues regarding the use of acupuncture as a therapeutic modality for osteoarthritis that are being examined include:

- Optimal number of acupuncture points
- Duration and frequency of treatment
- Independent and synergistic effects of needle placement on efficacy
- Appropriate research design and control strategies

The National Center for Complementary and Alternative Medicine (NCCAM) is one of the 27 institutes and centers that make up the National Institutes of Health (NIH). Studies of acupuncture for osteoarthritis are now being sponsored by NCCAM and NIH. Three pilot studies are presently funded and can be accessed by entering “acupuncture” and “osteoarthritis” in the searchable database of federally funded biomedical research projects provided by the Computer Retrieval of Information on Scientific Projects (CRISP) at http://crisp.cit.nih.gov/.

Grant # 5R01AT000304-02 “Efficacy of Acupuncture with Physical Therapy for Knee Osteoarthritis” focuses on the development of a properly designed and blinded RCT using ACR criteria and FDA recommended outcome measures. The study’s first major concern is that acupuncture’s effect may be predominantly mediated by non-specific placebo effects, rather than the specific effects of needle placement. Another important component of this study is the proposed use of a validated blinded placebo needle instead of sham acupuncture points. Since it is unclear whether acupuncture will provide additional clinically meaningful improvement in pain and function, the primary study goal will be to determine whether the addition of real acupuncture to standard exercise physical therapy provides improved outcomes compared to placebo/sham acupuncture. As a secondary goal, the clinical trial data will be used to develop prognostic and etiologic models for patients most likely to respond to acupuncture. The project began at the University of Pennsylvania in July 2001 and is scheduled to end March 2006.

Grant # 1R01AR049999-01 “Patient-Provider Interaction and Response to Acupuncture” focuses on the description and quantification of placebo effects in a trial of acupuncture for knee osteoarthritis. No previous studies have scientifically evaluated the effects of CAM providers’ communicative style and the placebo response that may result. This proposal will examine placebo responses in the context of practitioner-patient interactions at the time of the acupuncture treatment. Phase 1 will include a qualitative component to determine potential patient-related determinants of placebo response, such as beliefs and expectations towards treatment of knee osteoarthritis with acupuncture. Phase 2 will develop and test an instrument to measure evaluate outcome and self-efficacy expectations. Phase 3 will be a nested RCT to evaluate practitioner-patient interactions and placebo responses. Patients will initially be randomized to one of two different structures of practitioner-patient interaction. Acupuncturists will be trained to behave following semi-structured communicative styles, including traditional approaches in Chinese medicine and techniques previously described in patient-doctor communication studies. Within each of these groups, patients will be further randomized to receive real acupuncture or sham acupuncture. There will also be a natural control group (waiting list group), in which patients will be offered acupuncture three months after study entry. The project began at the Baylor College of Medicine in September 2002 and is scheduled to end August 2006.

Grant # 5U01AT000171-04 “Acupuncture Safety/Efficacy in Knee Osteoarthritis” deals with the establishment of a specialized center for research in complementary and alternative medicine (CAM) focusing on arthritis and related diseases. “The Center for Alternative Medicine Evaluation and Research in Arthritis” will support a multi-disciplinary team of researchers and develop institutional and regional collaborations to conduct clinical and basic research. Issues to be explored include the potential efficacy, safety and cost-effectiveness of long-term outcomes following acupuncture treatment for knee osteoarthritis. A single (not double) blind, three arm RCT using real acupuncture, sham acupuncture and an education/attention comparison group with total sample of 525 has been proposed. The primary hypothesis to be tested is that patients randomized to real acupuncture will have significantly more improvement in pain and function than patients randomized to sham acupuncture and education/attention control groups. Secondary aims of the study are to: 1) determine if improvement with acupuncture differs between patients below age 65 versus those aged 65 and above; 2) to determine if improvement with acupuncture differs by racial or ethnic group (Caucasian, Black, Hispanic); and 3) to determine if improvement with acupuncture differs by stage of baseline radiographic severity of knee osteoarthritis. This study is currently recruiting patients with: 1) knee osteoarthritis for at least 6 months duration; 2) at least moderate knee pain for most days in the last month; 3) current use of analgesic or nonsteroidal anti-inflammatory agents for control of pain; and 4) documented radiographic changes of osteoarthritis (Kellgren-Lawrence grade > 2) at time of rheumatological screening. Both genders, 50 years of age and above, are eligible. The project began at the University of Maryland Baltimore in September 1999 and is scheduled to end July 2004.

Ongoing Reviews

On October 21, 2002, NCCAM and 16 Federal co-sponsors announced that the Institute of Medicine (IOM), component of the National Academies, would study the scientific and policy implications of the use of complementary and alternative medicine (CAM) by the American public. NCCAM, the primary sponsor of the study, is the Federal Government's lead agency for scientific research on CAM. The National Academies is a private, nonprofit, non- governmental institution created by a congressional charter to be an advisory body for the nation on scientific and technological matters. The IOM draws upon volunteer panels of experts to examine policy matters regarding the public's health.

The IOM will assemble a panel of approximately 16 experts from a broad range of CAM and conventional disciplines, such as behavioral medicine, internal medicine, nursing, epidemiology, pharmacology, health care research and administration, and education. During the course of the study, the IOM panel will assess research findings, hold workshops, and invite speakers to address the panel, among other activities, in order to: 1) provide a comprehensive overview of the use of CAM therapies by the American public; 2) identify significant scientific and policy issues related to CAM research, regulation, integration, training, and certification; and 3) develop a conceptual framework to help guide decision-making on these issues and questions.

The IOM study committee will not be conducting new surveys of CAM use by the American public, nor will it assess the efficacy or safety of CAM products. Rather, the IOM panel will analyze existing data and will develop conceptual frameworks to guide decision-making on key issues and questions. Specifically, the Institute of Medicine (IOM) has been asked to form a committee to identify major scientific and policy issues in the following four areas:

- CAM research challenges and needs
- CAM regulation in the United States and other countries
- Interface and integration of CAM with conventional medicine

- Training and certification questions

The answers to these questions, and the information generated by the IOM panel of leading scholars drawn from both conventional medicine and CAM, will complement the WHCCAMP recommendations described just above in the previous section of this decision memorandum. The IOM project description, anticipated committee membership, upcoming meetings and additional information (as it becomes available) can be accessed by joining the CAM list serve or entering the keyword “CAM” on the IOM’s website.[35]

AHRQ, along with many other national organizations, is co-sponsoring the IOM study on acupuncture. Information about the IOM is available at http://www.iom.edu and about the National Academies at http://www.nationalacademies.org. NCCAM is likewise dedicated to exploring CAM practices in the context of rigorous science, training CAM researchers, and disseminating authoritative information to the public and professionals. Additional information about the NCCAM is available at http://www.nccam.nih.gov.

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” § 1862(a)(1)(A).

1. Strengths and Weaknesses of the Evidence

This decision memorandum focuses on: “Is there evidence of adequate methodological quality to conclude that the use of acupuncture significantly and reliably reduces pain in Medicare patients with osteoarthritis?”

In its Table 1, the NHS systematic review specifically commented upon two earlier reviews of acupuncture for osteoarthritis. The first of these by Ernst (1997) studied acupuncture as symptomatic treatment of osteoarthritis and found no evidence that acupuncture is superior to sham needling.[36] Ezzo, *et al*. (2001) also evaluated acupuncture as a pain treatment for knee osteoarthritis. Ezzo’s review found strong evidence that acupuncture is more effective than sham acupuncture, limited evidence that acupuncture is better than usual treatment, and insufficient evidence versus other treatments.[37]

Describing Ezzo *et al*'s (2001) review of 7 RCTs of knee osteoarthritis, the NHS concluded that evidence suggests that acupuncture may play a role in the treatment of knee osteoarthritis, particularly for the treatment of pain. Describing Ernst's (1997) review of 13 RCTs of osteoarthritis, the NHS stated that while both true and sham acupuncture reportedly improved symptoms, better RCTs suggested no difference between the two. Reiterating Ernst's conclusion, the NHS also noted that the belief that acupuncture is superior to sham needling is not supported by data from controlled clinical RCTs.[38]

AHRQ's search of the literature identified one additional systematic review by Berman, *et al.* (2000) on the use of acupuncture for osteoarthritis published since the 2001 NHS review. Berman observed that in all the studies that employed sham acupuncture as a placebo control, there were no significant between-group differences and none of the studies had sufficient power to detect a significant between-group difference (if one existed). In addition, Berman, *et al.* noted significant improvements in both sham and real acupuncture groups from baseline measurements.[39]

AHRQ also identified four recent RCTs of acupuncture for osteoarthritis[40,41,42,43] published since the 2001 NHS systematic review. Although reporting a significant improvement for at least two months in pain relief and function in the acupuncture group, Haslam (2001) noted a number of limitations with his RCT. Significantly, there was no acupuncture placebo group; sample size was small; and there were a high number of dropouts in the non-acupuncture group. Haslam also stated that for acupuncture to become a more accepted form of pain relief for hip osteoarthritis, further RCTs need to be undertaken with larger sample sizes, adequate control for the needling intervention and long-term follow-up.

In a re-analysis of patients previously studied and published elsewhere by Berman, *et al.* (1999), Singh, *et al*. (2001) concluded that those patients with the least disability and pain rebounded to a greater degree, suggesting that acupuncture should be used early in the treatment plan for patients with osteoarthritis. Demographic and medical history data were not mediating variables, but Singh, *et al.* recommended that larger studies should be undertaken in which a maintenance program is designed, influences of race and ethnicity are analyzed, and efficacy of acupuncture on cohort groups is measured. Singh and colleagues also stated that significantly larger sample sizes would be required to address these issues both within groups and between groups.

Tillu, *et al's* (2001) study concluded that unilateral acupuncture is as effective as bilateral acupuncture, but Tillu's study was similarly limited by the lack of adequate sham acupuncture or placebo control groups. Tillu and colleagues stated that their trial was not able to distinguish the specific needling effects from the non-specific placebo effects of the acupuncture treatment.

Fink, *et al's* (2001) study is believed to be the first prospective, randomized, controlled, patient and investigator-blinded clinical trial on the effectiveness of acupuncture for treatment of hip osteoarthritis, but the study did not include a third treatment arm of placebo acupuncture. This study's two treatment arms differed with regard to both location and manipulation of the needles, but a common feature of both treatments was needle insertion within the dermatomes of the affected hip region. Interestingly, Fink, *et al.* reported positive results regardless of the precise location and method of needle placement. Fink, *et al.* thus concluded that neither the rules of traditional acupuncture techniques nor any special knowledge of acupuncture was needed. This group was also unable to determine whether stimulation of mechanoreceptors or psychological effects of being treated were responsible for improvement reported following acupuncture.

CMS also identified a 2000 Bandolier analysis (a tertiary review of reviews) which commented that in Ernst's 1997 review:

- Most of the 13 clinical trials had used formula acupuncture (a pre-defined set of points) rather than traditional Chinese acupuncture.
- The majority of trials were of poor quality with severe methodological flaws.
- It was not clear from the review when or how outcomes were measured, whether results were statistically tested, or what diagnostic criteria of osteoarthritis were used.

The 2000 Bandolier review concluded that no difference has been shown between the effect of acupuncture and sham acupuncture for pain relief, and that the trials comparing acupuncture to active treatment controls were of insufficient methodological rigor to determine efficacy.[44]

Furthermore, there are serious questions about both the internal validity of reported results and the ability to generalize those results to clinical practice. In particular, experimental methods describing acupuncture treatments for osteoarthritis were inconsistent throughout the published literature and the type of acupuncture utilized in each study design was often not described in sufficient detail. Additionally, most studies reported results from skilled physician and non-physician acupuncturists in idealized, highly controlled settings. Both issues make generalization of acupuncture results difficult.

Another major concern is the association of positive patient expectations with placebo responses. That is to say, acupuncture's effect may be predominantly mediated by non-specific placebo effects produced by the therapeutic encounter itself, rather than specific effects produced by appropriate acupuncture needling. Placebo effects could include the amount of physical contact and relaxation experienced by the patient, the personality and perceived empathy of the acupuncturist, as well as patient expectations about the likely value of acupuncture. The nonspecific and specific effects of real and sham acupuncture procedures remain unclear.[45]

2. Conclusion

In summary, CMS concludes that the currently available evidence is insufficient to determine whether acupuncture has a specific beneficial effect for relief of pain in patients with osteoarthritis. While acupuncture may play an adjunctive role to medications for the treatment of pain, data from existing RCTs does not conclusively support that real acupuncture is superior to sham acupuncture for the pain associated with osteoarthritis. There are similarly no studies evaluating the best protocol or type of acupuncture for osteoarthritis. Overall, the poor quality of published data generally included a lack of adequate controls, non-standardized patient selection criteria, small sample size and limited follow-up. This absence of adequate methodological quality thus makes it difficult, if not impossible, to differentiate between true and false positive effects. Studies have not yet been properly designed or controlled to adequately demonstrate whether real acupuncture with standardized needling or non-needling techniques works better than placebo control or sham acupuncture, standard medical therapy or no therapy. These study design flaws presently prohibit determination of acupuncture's utility and make the evidence inadequate to determine that acupuncture for osteoarthritis improves health outcomes. CMS, therefore, concludes that this intervention is not reasonable and necessary.

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1 http://www.rheumatology.org/research/guidelines/oa-mgmt/oa-mgmt.html

2 *De qi* is a sensation of numbness, tingling, electrical sensation, fullness, distension, soreness, warmth or itching felt by a patient around an acupuncture point. Whether it is necessary to elicit *de qi* to render a treatment effective remains controversial among acupuncturists. Alberta Heritage Foundation for Medical Research (AHFMR) Health Technology Assessment 2002

3 Microcurrent stimulation and electroacupuncture involve introduction of an electrical current to the inserted needles at various frequencies. The Chinese term *zhenjiu*, referencing both acupuncture and moxibustion, involves warming of the needles by burning the dried herb *Artemisia vulgaris* (mugwort) over the acupuncture point. Staple acupuncture involves application of a metal staple for a prolonged period of time to an acupuncture point. Cupping acupuncture involves application of vacuum force to acupuncture points. Acupressure (without needles) involves the stimulation of an acupuncture point manually with pressure with the intention of stimulating *qi* flow. Laser acupuncture involves stimulation by a laser beam directed at the acupuncture point. Fire needling involves inserting red-hot needles at acupuncture points. AHFMR Health Technology Assessment 2002

4 Eisenberg, *et al.* 2002

5 ibid.

6 http://www.abms.org/links.asp

7 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=880.5580

8 http://www.fda.gov/bbs/topics/ANSWERS/ANS00722.html

9 AHFMR Health Technology Assessment 2002

10 Gallagher, *et al.* 2001

11 Bellamy, *et al.* 1988

12 Lequesne 1991

13 Jadad, *et al.* 1996

14 United Kingdom NHS Review 2001

15 AHFMR Health Technology Assessment 2002

16 Ernst 1997

17 Ezzo, *et al.* 2001

18 Ernst 1997

19 Takeda and Wessel 1994

20 Christensen, *et al.* 1992

21 Berman, *et al.* 1999

22 Berman, *et al*. 2000

23 Christensen, *et al.* 1992

24 Berman, *et al.* 1999

25 Junnila 1982

26 Haslam, *et al.* 2001

27 Singh, *et al.* 2001

28 Tillu, *et al.* 2001

29 Fink, *et al.* 2001

30 Haslam 2001

31 Berman, *et al.* 1999

32 Singh, *et al*. 2001

33 Tillu, *et al*. 2001

34 Fink, *et al.* 2001

35 http://www.iom.edu/iom/iomhome.nsf/SearchView/$SearchForm?SearchView

36 Ernst 1997

37 Ezzo, *et al.* 2001

38 United Kingdom NHS Review 2001

39 Berman, *et al.* 2000

40 Haslam, *et al.* 2001

41 Singh, *et al.* 2001

42 Tillu, *et al.* 2001

43 Fink, *et al.* 2001

44 http://www.jr2.ox.ac.uk/bandolier/booth/alternat/AT008.html

45 AHFMR Health Technology Assessment 2002

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